
Talking With Family PACT Clients About HPV Immunization

August 17, 2022



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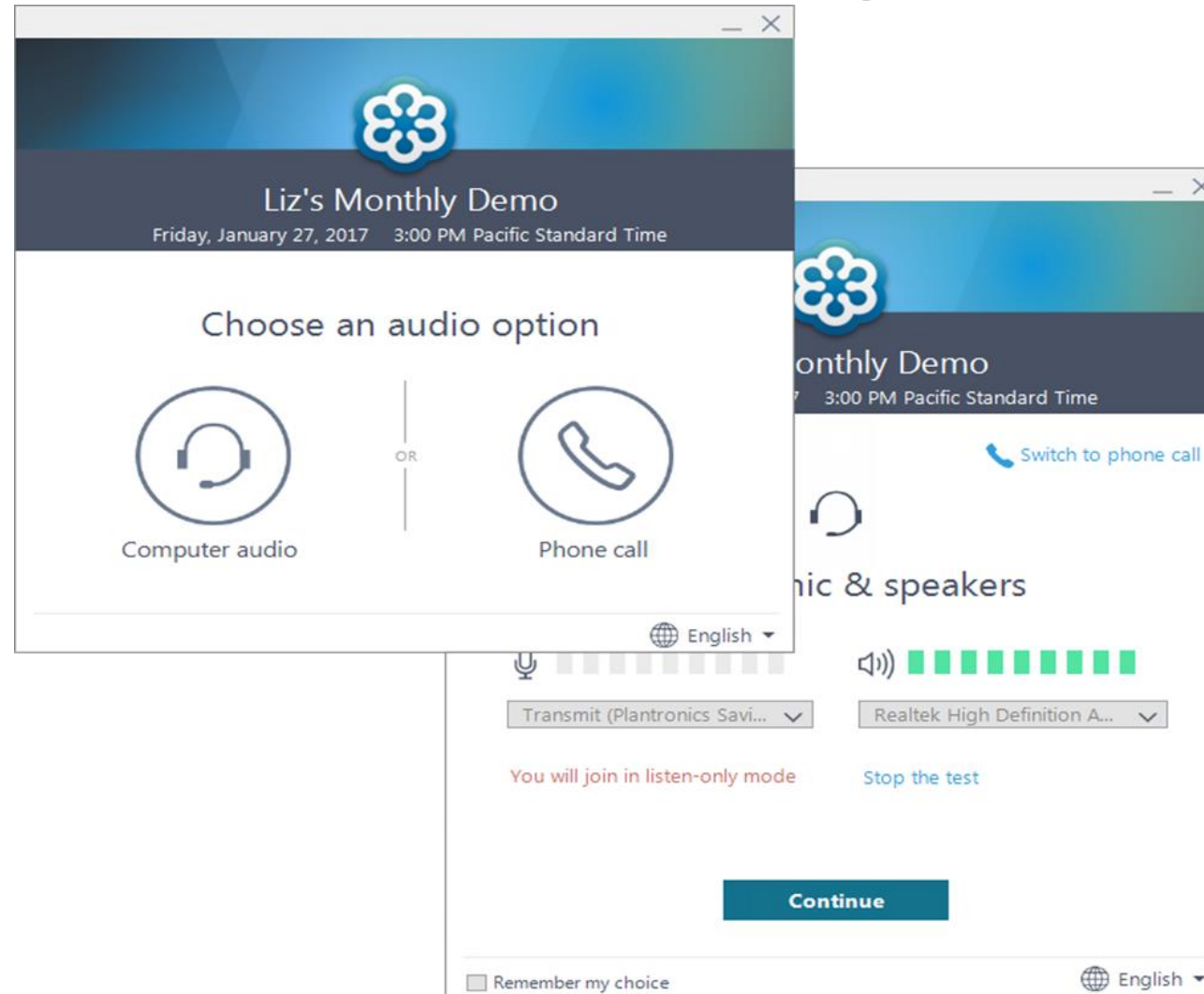
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UCLA School of Nursing
President, Envision SRH



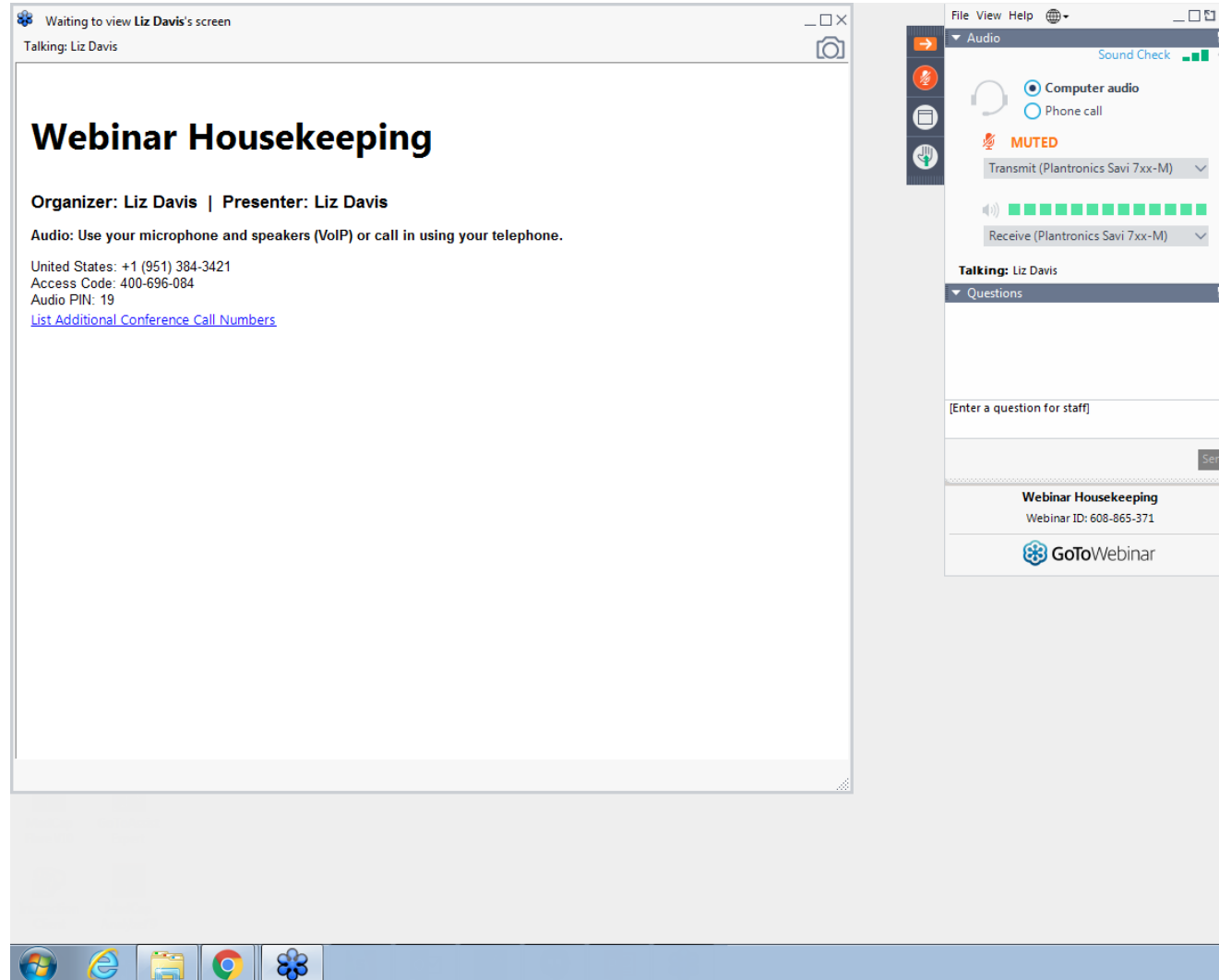
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Medical Consultant, Office of Family
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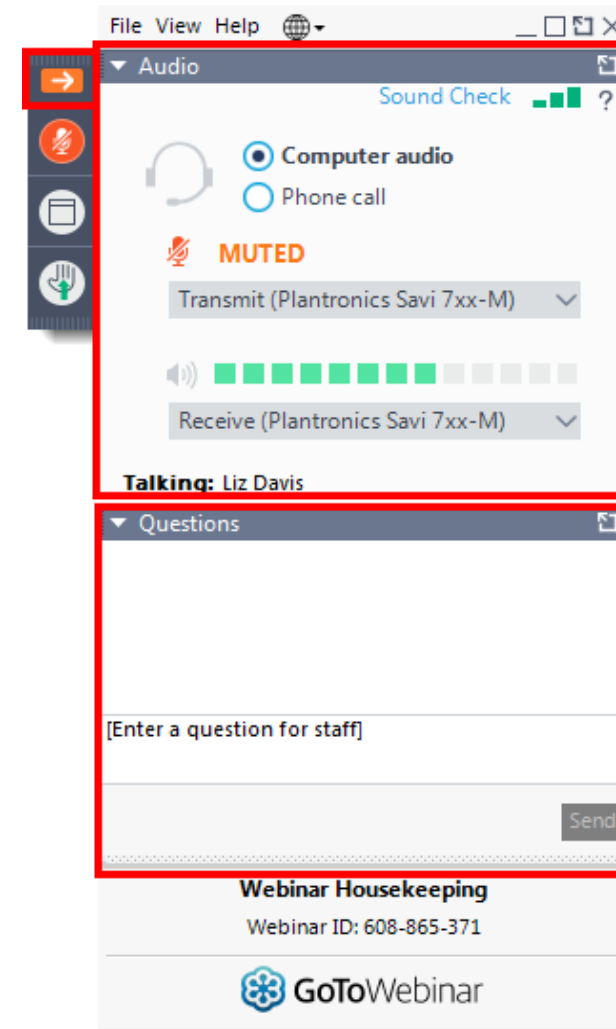


GoToWebinar Housekeeping: Attendee Participation

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Learning Objectives

- List 2 effective strategies for engaging with patients who have vaccine hesitancy
- Demonstrate a person-centered technique for providing a strong recommendation without coercion
- Describe the impact of HPV vaccination on the natural history of HPV
- Discuss the safety profile of HPV vaccines



HPV ~~Vaccination~~ Immunization

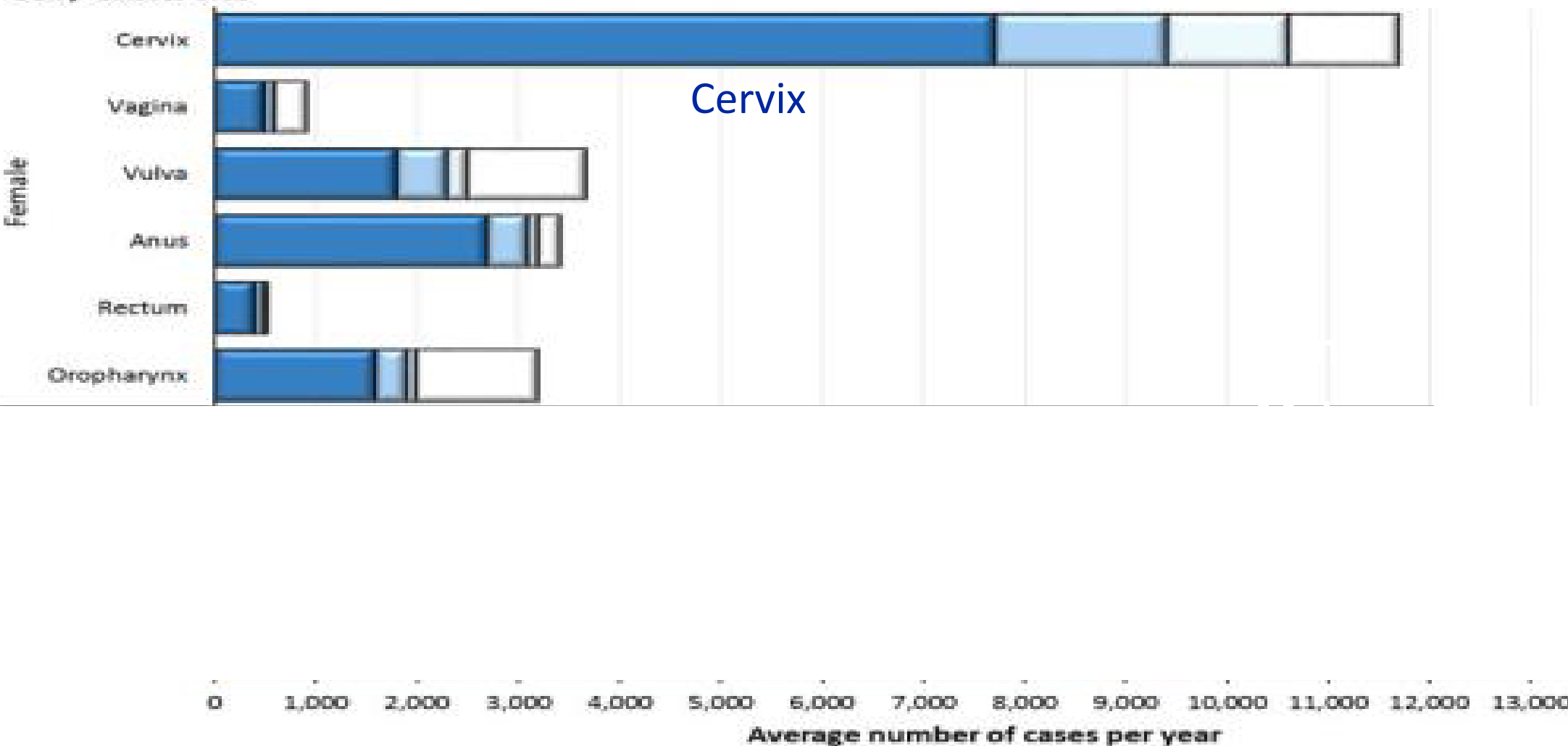
On-line search

- The word “vaccine” yields anti-vaccine links
- The word “immunization” yields scientific information

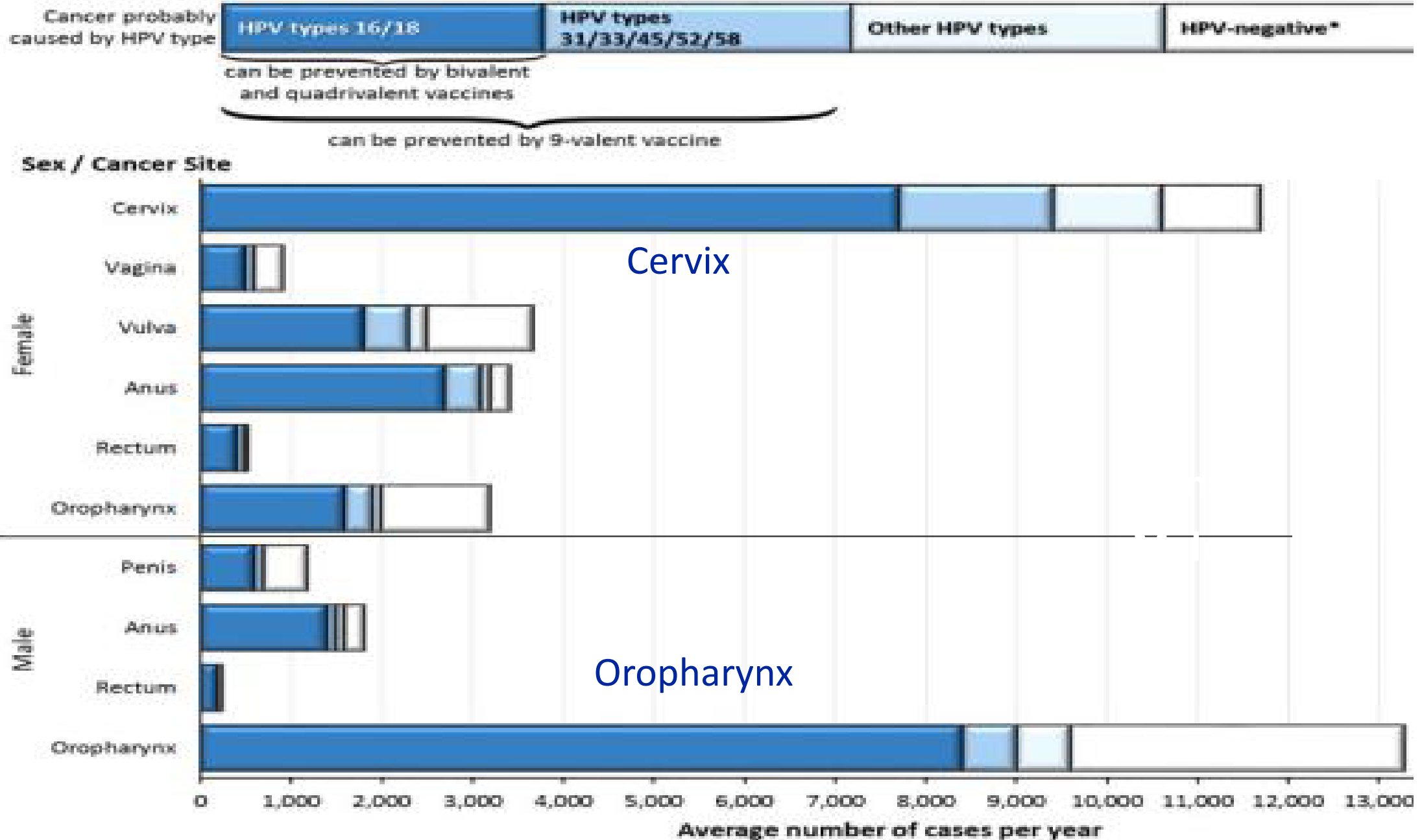
Cases prevented by 9vHPVV



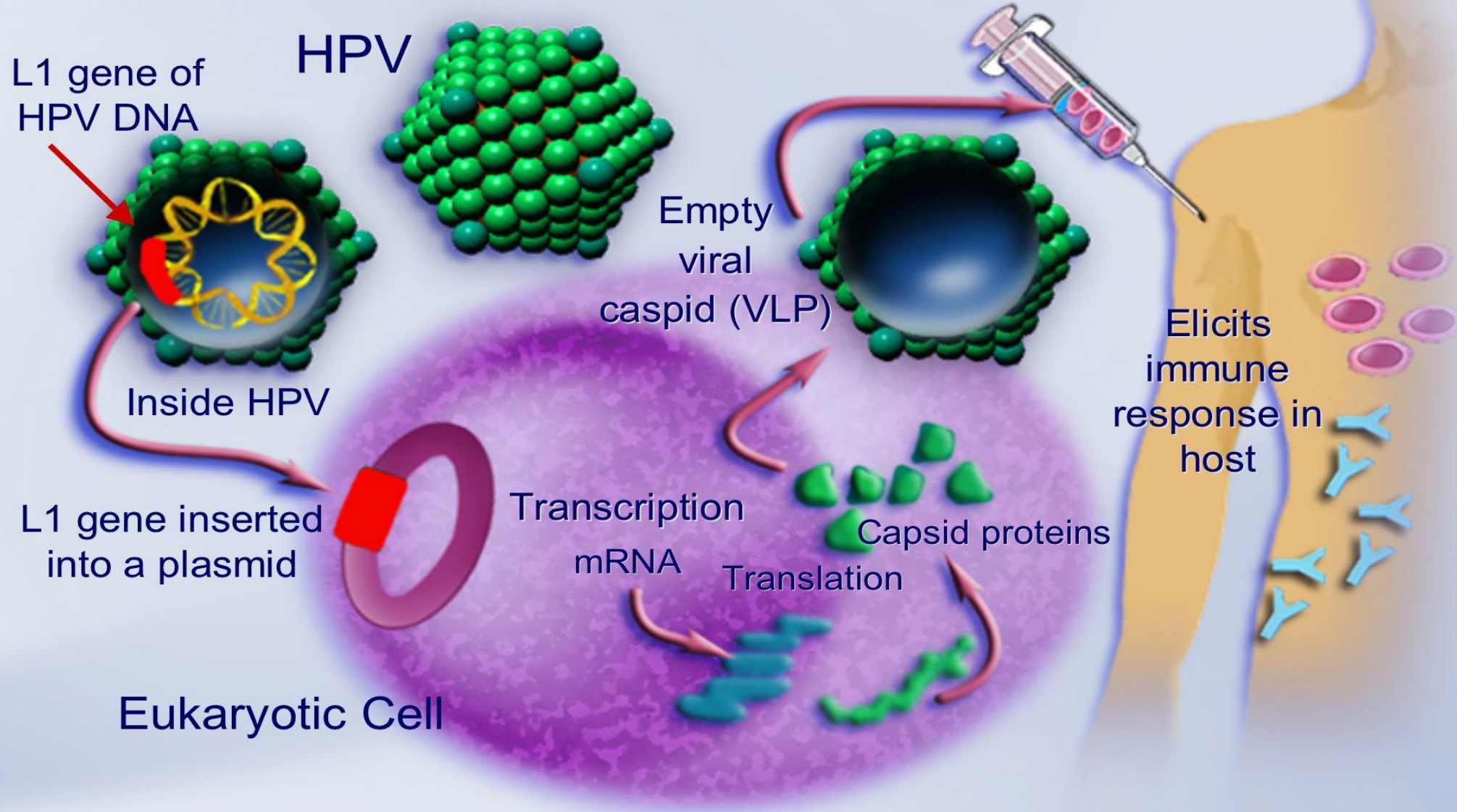
Sex / Cancer Site





Cases prevented by 9vHPV



HPV L1 Virus-Like-Particle (VLP) Vaccine Synthesis

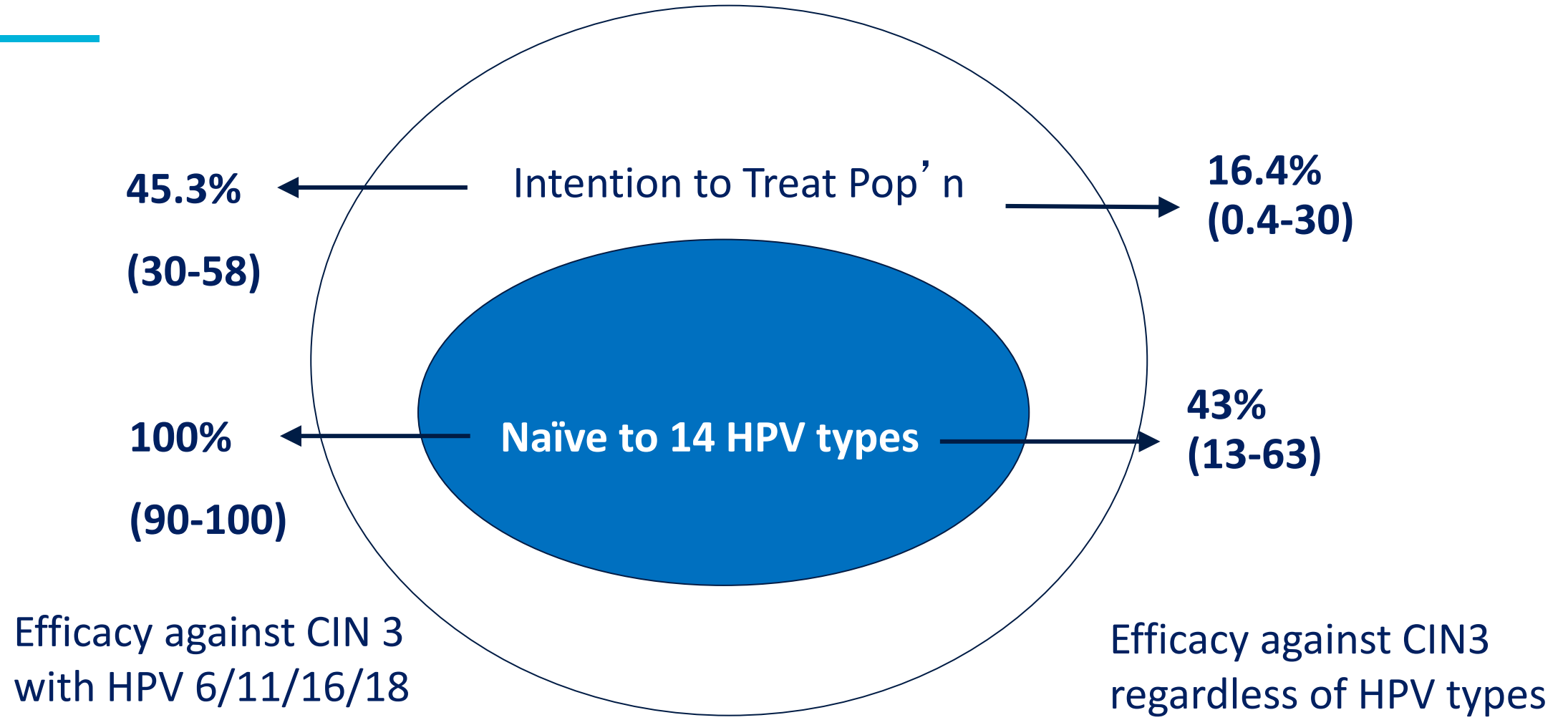


HPV Vaccines

	Brand name	HPV types	Doses	Age range	US
4vHPV 	Gardasil™ (Merck)	6, 11 16, 18	3	9-26	2006
2vHPV 	Cervarix™ (GSK)	16, 18	3	9-25	2009
9vHPV	Gardasil-9™ (Merck)	6, 11, 16, 18, 31, 33, 45, 52, 58	2 3	9-14 15-26	2015

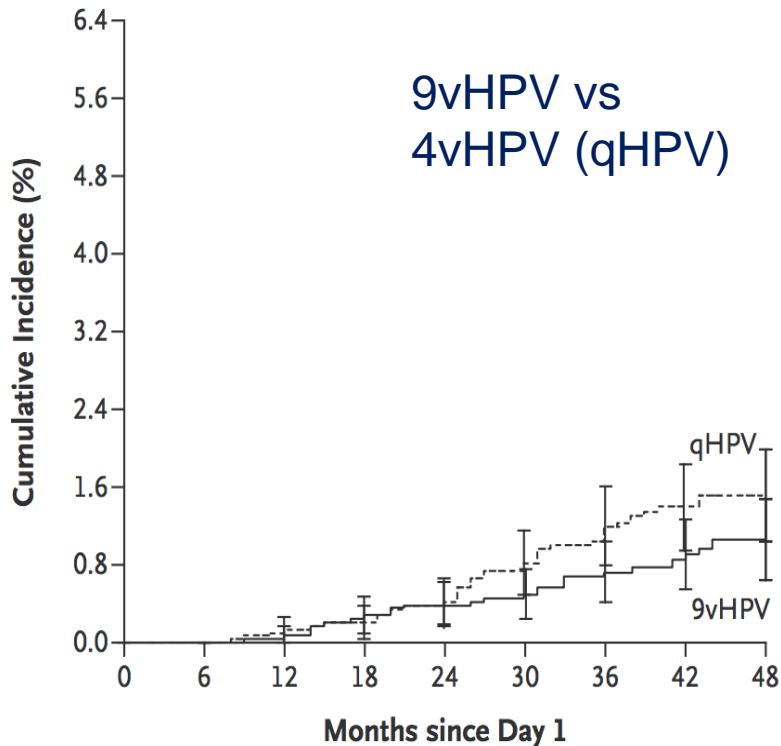
Efficacy: *Quadrivalent Vaccine*

Munoz et al JNCI 2009



Not HPV infected on Day 1

C High-Grade Cervical Disease Irrespective of HPV Type among Participants Not HPV-Infected on Day 1



No. at Risk

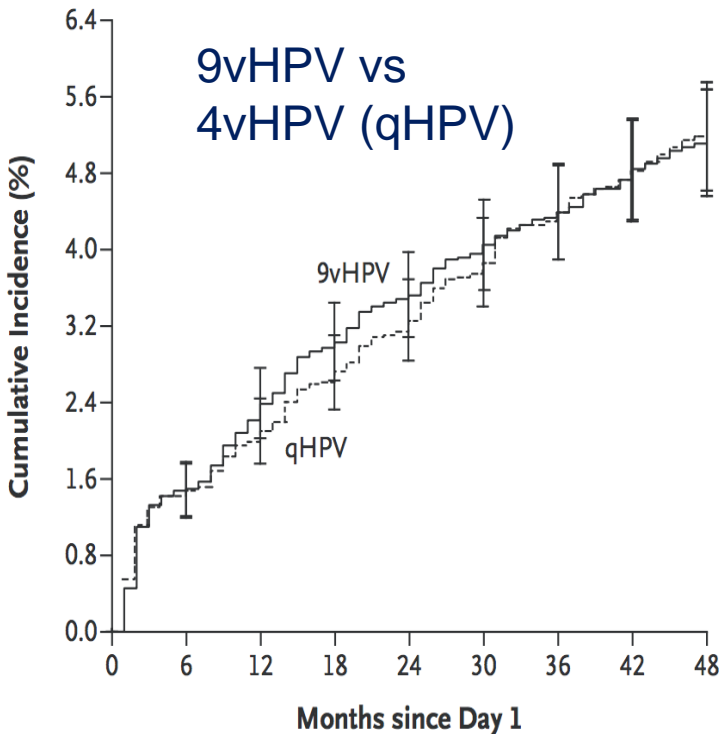
9vHPV	2976	2957	2859	2787	2715	2625	2466	1537	432
qHPV	3009	2992	2909	2826	2749	2680	2528	1580	490

Cumulative Cases

9vHPV	0	0	2	8	11	14	20	24	26
qHPV	0	0	4	6	12	23	33	38	40

All trial participants

D High-Grade Cervical Disease Irrespective of HPV Type in the Modified Intention-to-Treat Population



No. at Risk

9vHPV	6882	6710	6449	6253	6079	5853	5483	3487	964
qHPV	6871	6700	6475	6286	6093	5899	5552	3532	1039

Cumulative Cases

9vHPV	0	103	163	205	237	270	290	314	322
qHPV	0	101	143	184	219	257	289	312	323

How Effective is HPV Immunization in Females 15-26?

	Cases/10K Immunized	Cases/10K Placebo
HPV naïve, CIN 3+, 16/18+	0	70
HPV naïve, AIS, 16/18+	0	9
HPV naïve, CIN 3+, all HPV types	106	287
HPV naïve, AIS, all HPV types	0	10
Any HPV status, CIN 3+, 16/18+	91	165
Any HPV status, CIN 3+, all HPV types	178	266
Any HPV status, AIS, 16/18+	5	14
Any HPV status, AIS, all HPV types	5	17

ACIP: Routine HPV Immunization



Females: HPV Immunization with 9vHPV

Routine: 11- or 12-year-olds

Males: HPV Immunization with 9vHPV

Routine: 11- or 12-year-olds

Vaccination of Boys and Men: Why??



- Prevention of
 - HPV-associated cancers: anal, penile, oropharyngeal; mainly HPV 16
 - Genital warts
 - Transmission of hrHPV to sexual partners
- 2009: 4vHPV licensed in males to prevent genital warts
- 2010: FDA added indication of prevention of anal cancer
- 2011: 4vHPV and 9vHPV recommended by ACIP for males
 - Licensed in same age range as females

ACIP: Routine HPV Immunization



- The series can be started as early as age 9 years
- Offer catch-up immunization to females and males 13-26 years olds
- Immunization is not recommended for everyone *older than age 26 years*
 - Some adults ages 27-45 years of age might decide to get the HPV vaccine based on discussion with their clinician, if not adequately immunized
 - Clinicians can consider discussing HPV immunization with people who are most likely to benefit. It does not need to be discussed with most people



ACIP: Routine HPV Immunization

- Each dose is 0.5 mL, administered IM
- 2006: administered in a 3-dose schedule
 - 2nd dose: 1-2 months after 1st dose
 - 3rd dose: 6 months after 1st dose
- 2016: TWO dose schedule in 9 through 14-year-olds
 - Zero and 6-12 months
- Can give with other vaccines (TDaP, TD, MCV4)
- Avoid if a hypersensitivity to yeast or any vaccine component

ACIP: Routine HPV Immunization

Candidates for HPV immunization

- Women who have abnormal cervical cytology, a positive HPV DNA test, or genital warts
- Lactating women
- Immunocompromised females
 - But immune response and vaccine effectiveness might be less than in immunocompetent women

ACIP: Routine HPV Immunization

- 9vHPV may be used to continue or complete a vaccination series started with 4vHPV or 2vHPV
- For persons adequately vaccinated with 2vHPV or 4vHPV, there is no ACIP recommendation regarding additional vaccination with 9vHPV
- If the schedule is interrupted, the vaccination series does not need to be restarted

ACIP: Routine HPV Immunization

- If providers do not know or do not have available the HPV vaccine product previously administered, *any available HPV vaccine* product may be used to continue or complete the series for *females* for protection against HPV 16+18
- 9vHPV or 4vHPV may be used to continue or complete the series for *males*

ACIP: Routine HPV Immunization

- HPV vaccines are not recommended for use in pregnant women
- If pregnant after initiating the vaccination series, the remainder of the 3-dose series should be delayed until completion of pregnancy
- Pregnancy testing is not needed before vaccination
- If a vaccine dose given during pregnancy, no intervention is needed
- A pregnancy registry is available for 9vHPV
 - Pregnancy registries for 4vHPV and 2vHPV have been closed

ACIP: Routine HPV Immunization

Cervical cancer screening

- No changes in screening is recommended based on vaccination status
- Recommendations will continue to be evaluated as further post licensure monitoring data become available

HPV Immunization: Adverse Effects

- Injection-site reactions (pain, redness, swelling in the upper arm)
- Headache
- Vasovagal: dizziness, fainting, nausea
 - Sitting or lying down for about 5-10 minutes after a vaccination can help prevent fainting and injuries that can be caused by falls

Vasovagal Prevention



Anticipatory
guidance

Cross legs
and contract
opposite
arm



Good
hydration
(electrolyte/
sports drink)

Eat before
injection



Pre-syncopal Symptoms

- Weakness
- Light-headedness
- Diaphoresis
- Visual blurring
- Headache
- Nausea
- Feeling warm or cold
- Sudden need to go to the bathroom

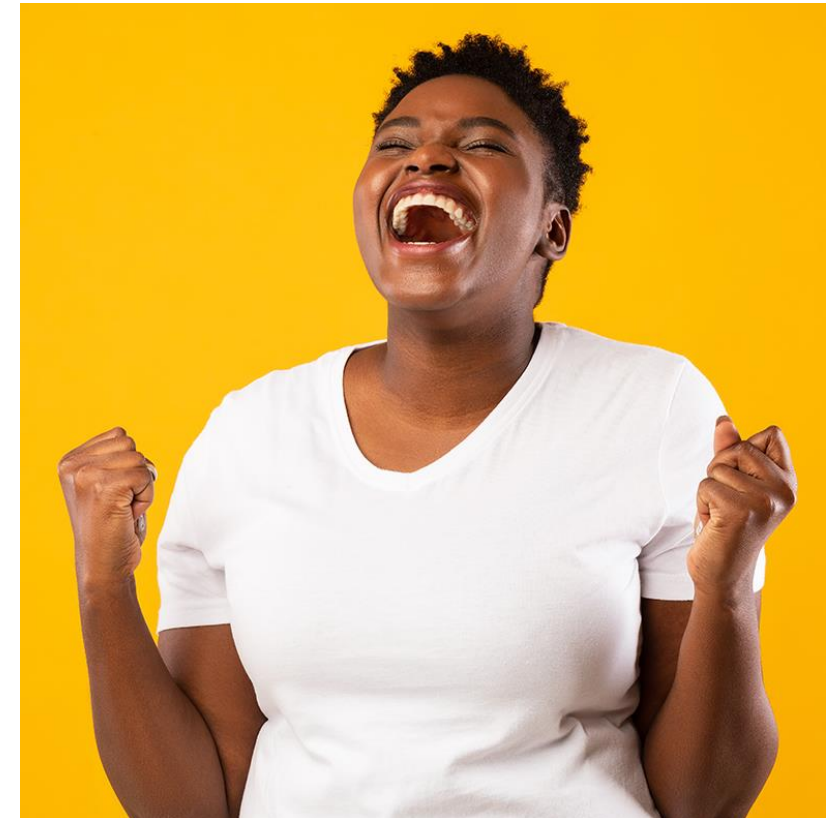
Pre-syncopal Signs

- Facial pallor
- Yawning
- Pupillary dilatation
- Nervousness



How to Avert a Vasovagal

- Isometric contractions of the extremities
- Intense gripping of the arm, hand, leg and foot muscles
- No need to change position— just tense the muscles
- **This stops the reaction**



Anticipatory Guidance

Many people getting an injection feel dizzy and can even faint. If that happens it can be scary!

But you can stop it from happening!



Anticipatory Guidance

If you start to feel light-headed, or nauseated, or if you just feel weird in any way... tense the muscles in your hands, arms, feet, and legs and it will stop. Try it now--to practice.



10/5/18: FDA Approves Gardasil 9 for 27-45 Year Olds

- 9vHPV studied in 3,200 women 27-45 for 3.5 yrs
 - 88% decrease in persistent infection, genital warts, precancerous cervical, vaginal, vulvar lesions (covered types)
- In men 27-45 years, approval was based upon
 - Efficacy data in women for this age group
 - Earlier trials in boys and younger men
 - Immunogenicity data from 150 men in older age group

FDA Approval of Gardasil 9 for 27-45 Year Olds

- Why does it work in older individuals?
 - Even if previously exposed to a few types, can gain protection against HPV types not yet encountered
- CDC ACIP guidance
 - Permissive for 27-45 y.o. (...use shared decision making)
 - Not subject to the “no cost-sharing” feature of the ACA for ACIP recommended vaccines

9vHPV Vaccine for 27-45 Year Olds



2019

- Catch-up HPV vaccination is not recommended for all adults aged >26 years
- Shared clinical decision-making regarding HPV vaccination is recommended for some adults aged 27- 45 years who are not adequately vaccinated.
- HPV vaccines are not licensed for adults older than 45 years old

ACOG Guidelines for HPV Vaccination

- OBGs and other HCPs should *strongly recommend* HPV vaccination to eligible patients and stress the benefits and safety of the HPV vaccine
- Educate parents re: vaccinations for all children
- For some individuals aged 27–45 years, use shared clinical decision making
- OBGs are encouraged to *stock and administer* HPV vaccine in their offices
- HPV vaccine can and should be given to people who are lactating aged 26 years and younger who have not previously been vaccinated

NIH Guidelines for HPV Vaccination in People with HIV (PWH)

- HPV vaccination is recommended PWH aged 13-26.
- Among PWH, data do not support routine vaccination if > 26 years old
 - Shared clinical decision-making is recommended as it is with other 27-45-year-old individuals
 - The public health benefit for HPV vaccination in this age range is minimal

<https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/human-0?view=full>

HPV Vaccine Coverage (Age 13–17 Years) Is Less Than Other Adolescent Vaccines

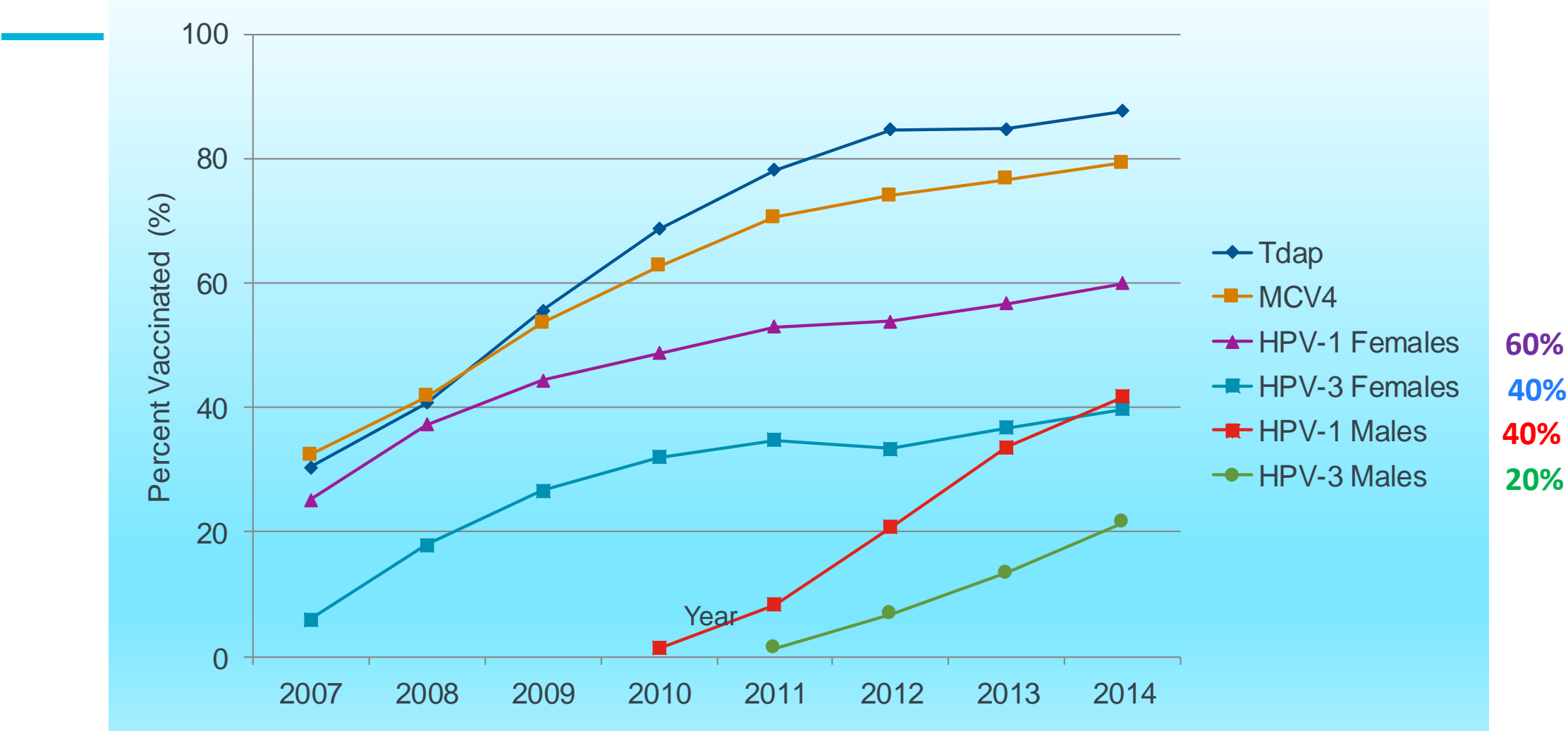
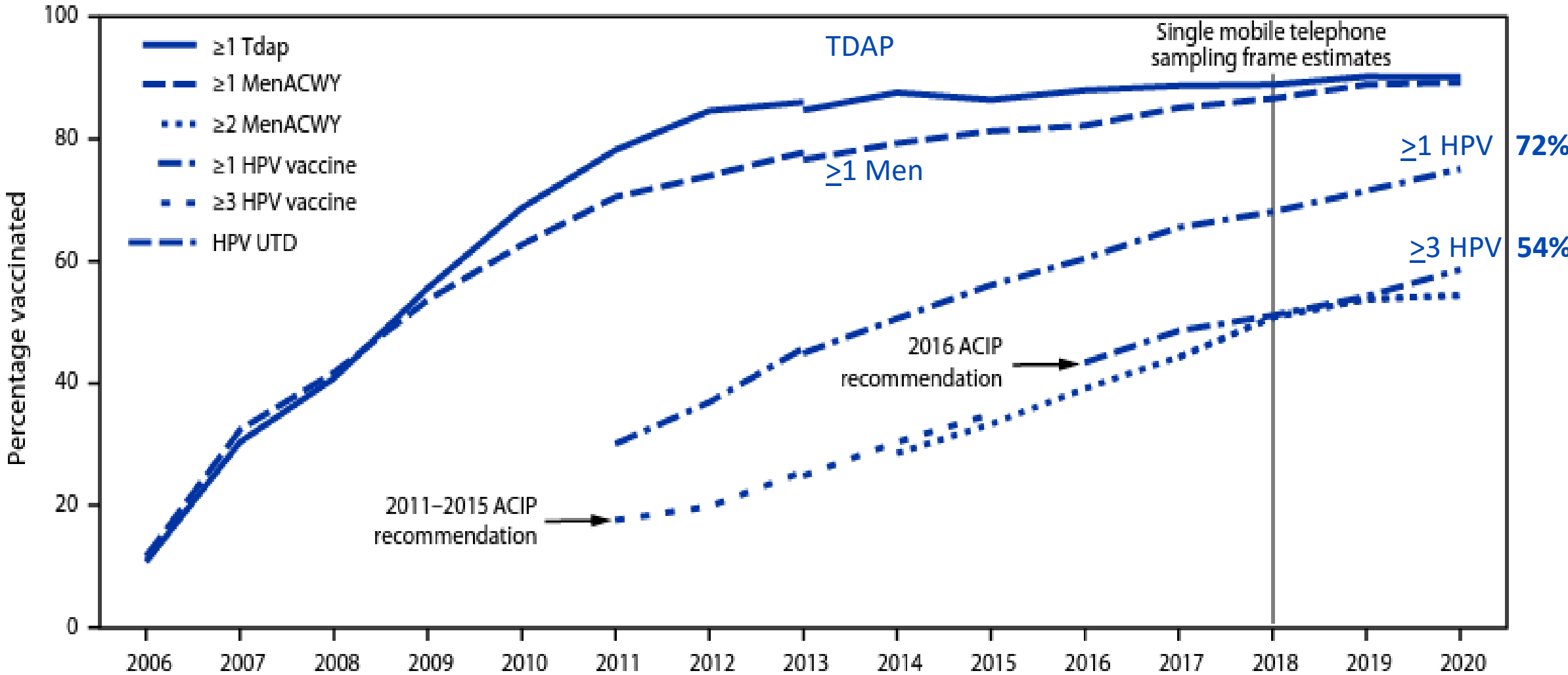


FIGURE. Estimated vaccination coverage with selected vaccines and doses* among adolescents aged 13–17 years, by survey year† — National Immunization Survey–Teen,^{§,¶} United States, 2006–2020



Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine
MenACWY = quadrivalent meningococcal conjugate vaccine

The projected timeframe until cervical cancer elimination in Australia: a modelling study

Michaela T Hall, Kate T Simms, Jie-Bin Lew, Megan A Smith, Julia ML Brotherton, Marion Saville, Ian H Frazer, Karen Canfell

- If high-coverage vaccination and screening is maintained, at an elimination threshold of 4 new cases/100,000 women annually, cervical cancer could be eliminated as a public health problem in Australia within the next 20 years
- However, screening and vaccination initiatives would need to be maintained thereafter to maintain very low cervical cancer incidence and mortality rates

Family PACT Benefit for HPV Vaccination

- Coverage is restricted to individuals 19 to 45 years of age.
- Use the following CPT codes for HPV vaccine and administration
 - 90651: 9vHPV vaccine
 - 90471: Immunization administration
- For individuals 27-45 years of age, the CDC ACIP recommends vaccination based on *shared decision-making*
 - The shared decision-making discussion must be documented
- Bill with the ICD-10 code that identifies the client's contraceptive method
 - Not reimbursable with diagnosis codes Z30.012, Z30.09, or Z31.61

Counseling About HPV Immunization

doi: [10.15585/mmwr.mm6832a3](https://doi.org/10.15585/mmwr.mm6832a3).

Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices

[Elissa Meites](#), [Peter G Szilagyi](#), [Harrell W Chesson](#), [Elizabeth R Unger](#), [José R Romero](#),
[Lauri E Markowitz](#)

PMID: 31415491 PMCID: [PMC6818701](#) DOI: [10.15585/mmwr.mm6832a3](https://doi.org/10.15585/mmwr.mm6832a3)

Free PMC article

**BOX. Considerations for shared clinical decision-making regarding
human papillomavirus (HPV) vaccination of adults aged 27 through 45**

ACIP Makes Shared Clinical Decision-Making (SDM) Recommendations

When individuals may benefit from vaccination, but it is unlikely to have population-level benefit

- 6/2019, ACIP recommended SDM for HPV vaccination of adults aged 27–45
- Most in this age group would have no or minimal benefits from vaccination
- Individuals who may benefit:
 - Have or plan to or hope to have new sexual partner(s)
 - Not already immune to HPV through vaccination or natural infection
 - A previously unvaccinated person who has never had sex
 - At risk for acquiring a new HPV infection in the future

- HPV is a very common STI.
- Most HPV infections are transient and asymptomatic and cause no clinical problems.
- Some adults are at risk for acquiring new HPV infections.
- At any age, having a new sex partner is a risk factor for acquiring a new HPV infection.
- Persons who are in a long-term, mutually monogamous sexual partnership are not likely to acquire a new HPV infection.
- Most sexually active adults have been exposed to some HPV types, although not necessarily all the HPV types targeted by vaccination.

- No clinical antibody test can determine whether a person is already immune or still susceptible to any given HPV type.
- HPV vaccine efficacy is high among persons who have not been exposed to vaccine-type HPV before vaccination.
- Vaccine effectiveness might be low among persons with risk factors for HPV infection or disease (e.g., adults with multiple lifetime sex partners and likely previous infection with vaccine-type HPV), as well as among persons with certain immunocompromising conditions.
- HPV vaccines are prophylactic.

ASCCP Practice Committee Opinion: HPV Vaccination in Previously Unvaccinated Individuals Undergoing Treatment for CIN2+

- Consider the benefit of HPV vaccination for individuals aged 27-45 undergoing treatment for CIN2+.
- Offer HPV vaccination to previously unvaccinated 27–45-year-olds with a history of CIN2+ regardless of whether they are undergoing surgical treatment.
- These individuals should be counseled.
 - Prophylactic vaccine will not treat existing HPV disease or prevent all future HPV-related disease.
 - Continued surveillance is important.

ASCCP Practice Committee Opinion: HPV Vaccination in Previously Unvaccinated Individuals With HPV-Related Diseases

Role of Adjuvant HPV Vaccination in Previously Unvaccinated Individuals with vulvar intraepithelial neoplasia (VIN), vaginal intraepithelial neoplasia (VAIN), high-grade anal intraepithelial neoplasia (AIN), and anogenital warts

- Offer HPV vaccine as there is possible benefit in reducing the risk of recurrence in treated individuals.

Recommendation to Immunize HCPs

- ASCCP issued a statement in February 2020 recommending HPV vaccination for medical professionals who are routinely exposed to the virus through their occupation.
- <https://www.asccp.org/hpv-vaccination>



Improving lives through the prevention and treatment of anogenital & HPV-related diseases

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February 19, 2020

Dear Members,

Supporting our mission of prevention and treatment of HPV-related diseases, ASCCP announces a call to members recommending HPV vaccination for clinicians routinely exposed to the virus.

This recommendation encompasses the complete provider team, including but not limited to, physicians, nurse practitioners, nurses, residents, and fellows, as well as office and operating room staff in the fields of obstetrics and gynecology, family practice, gynecologic oncology, and dermatology.

In 2018, the U.S. Food and Drug Administration approved a supplemental application for Gardasil 9, expanding the approved use of the HPV vaccine to include persons aged 27 to 45 years old. While there is limited data on occupational HPV exposure, ASCCP, as well as other medical societies, recommend that members actively protect themselves against the risks.

As the leader in anogenital and HPV-related diseases, ASCCP will continue to research and educate you on the potential health risk from HPV exposure.

Colleen K. Stockdale, MD, MS
2019-2020 ASCCP President

Mark H. Einstein, MD, MS
2019-2020 ASCCP President-Elect

Warner K. Huh, MD
2019-2020 ASCCP Immediate Past President



Words to Avoid

**Widely used vaccination terms
may elicit strong reactions and consequences**

“vaccine hesitancy” “anti-vaccine”

“anti-vaxxer”

“herd immunity”

“mandatory vaccination”

Dudley, M. (2020) *Vaccine*

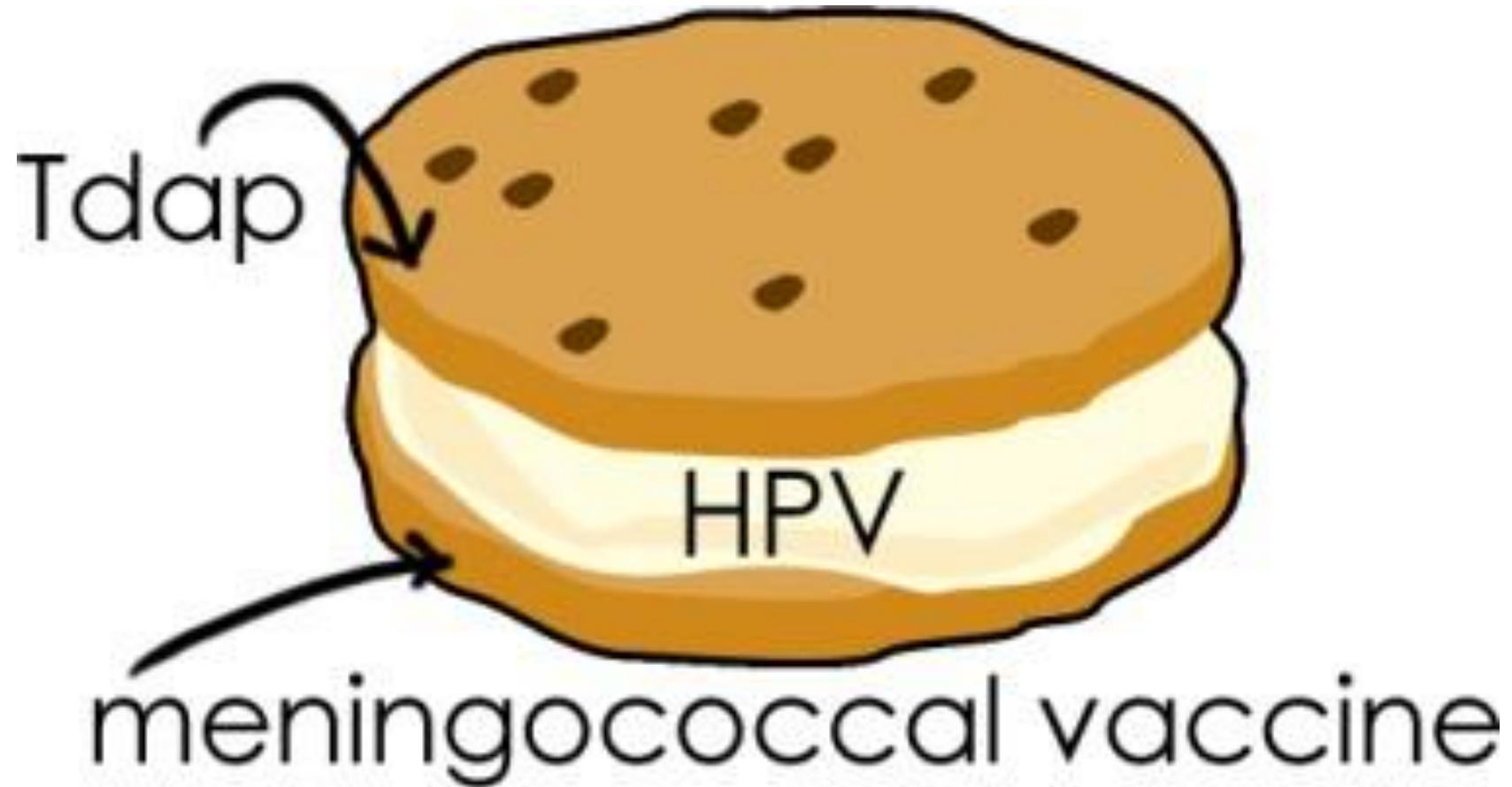
Three-Tiered Strategy

1. Default is to vaccinate
2. Provider recommendation
3. Shared decision making and client centered counseling to address barrier

Routine Immunization

- The default is to vaccinate the patient based on age, catch-up, or based on risk unless they opt out or it is contraindicated.
- The less discussion the better.
- Present in the same way as other routine health care maintenance “you are due.”
 - Immunizations like Flu, TDAP, meningococcal
 - or in the same way as routine screening
- Do not present it as “different” than other immunizations.

“Today, you are due for: Tdap, HPV, and MCV4.”



Rationale

- We don't describe or discuss influenza, meningococcal vaccine, TDAP or other vaccines like we do HPV.
- We don't have a conversation with the patient (or parent) about behaviors with any other vaccine.

Fear

- Fear of sexual topics
- Fear of adverse effects
- HCP afraid to bring it up and offend
- HCP concerned there is inadequate time to manage the pushback

AFFIRM – SHARE – ASK (ASA) CYCLE





AFFIRM/ ACKNOWLEDGE

1ST STEP

START with either:

- Agreement
- Display of empathy
- Validation
- Strength-based positive



First step is to find something in what the client is saying to agree with or support

Avoid saying “No” or “But”

“Yes! And _____”

Empathy Without **Labeling** Feelings

Rather than using a negative label:

- “You sound angry.” (or anxious)

Use neutral words:

- “It sounds like this is really concerning to you.”
- “Wow, anyone would find that really hard to deal with!”
- “Wow...”

Not: “I know how you feel.”

(Hatcher. 2018)

Validation

“I hear that all the time!”

“I can understand why
you would think that!”

“Lots of people have that question.”



SHARE INFORMATION



Support Integration of New Knowledge

- Present information that is relevant to the individual.
- Use plain language.
- Limit the amount of information.
- Use the patient's words.
- Use 5 out of 100 people rather than 5%.

Paraphrasing

“So I hear you saying ...(you are concerned that your daughter will be inclined to have sex at a younger age if she gets this vaccine) do I have that right?”

“It sounds like you....(really want to know that this vaccine is safe) is that what you mean?”

This is an Immunization Against Cancer

Put risk into a disease perspective—
It's about preventing cancer. It's not
about sex.

Many misperceptions:

- Safety
- Will increase sexual promiscuity
- Not needed



Offit P. (2014) New York Times.

“HPV Immunization Prevents...”

- HPV vaccine protects against cervical cancer, vaginal cancer, vulvar cancer, penile cancer, anal cancer and throat cancer.
- Every year, over 27,000 individuals are affected by a cancer caused by HPV—that's a new case every 20 minutes.
- Most of these cancers could be prevented by HPV vaccination.

Personal Benefit

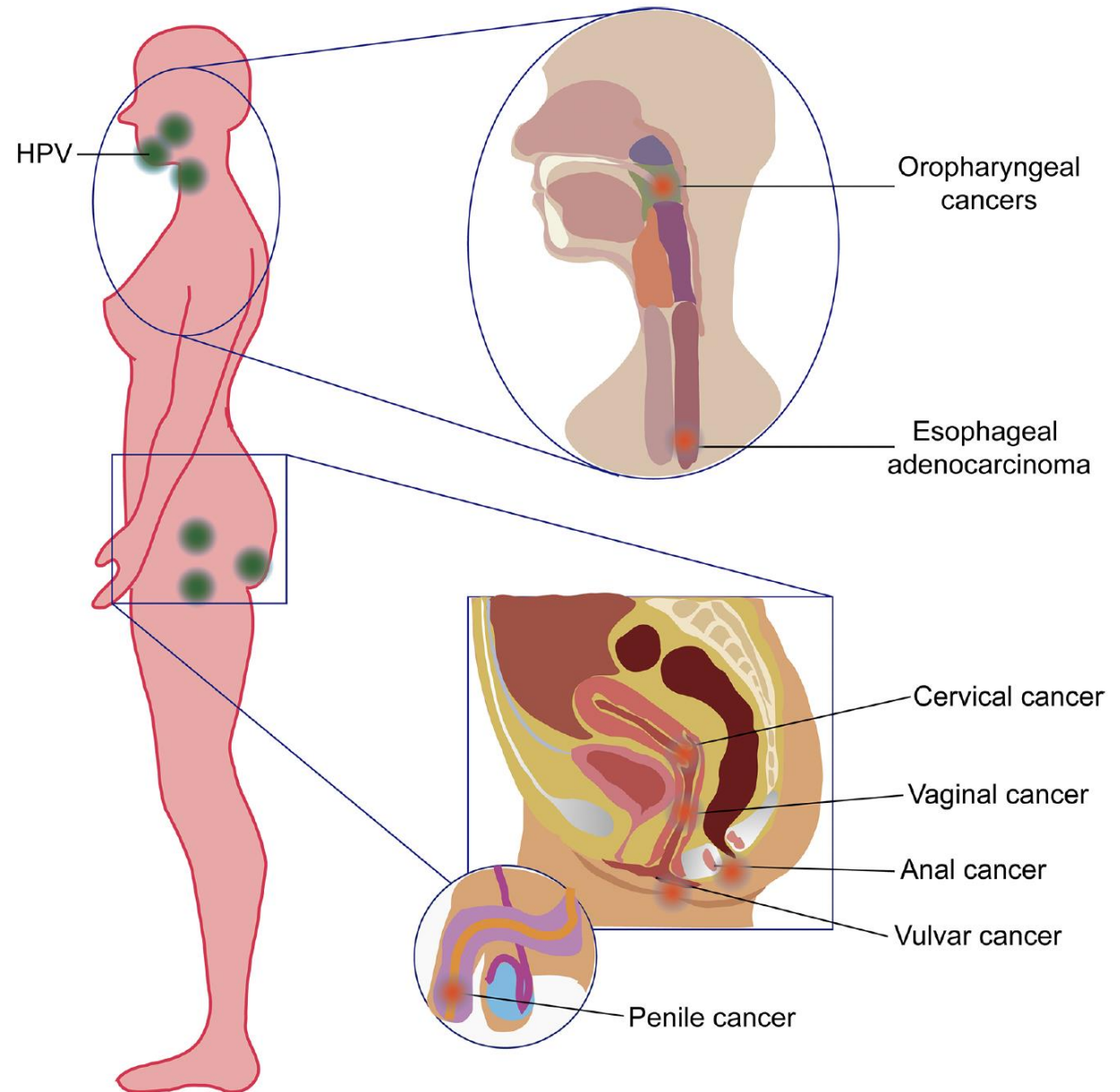
- Most of us will never be exposed to tetanus or polio in our lifetimes, yet we don't question protecting our children and ourselves from those infections

Deaths from:

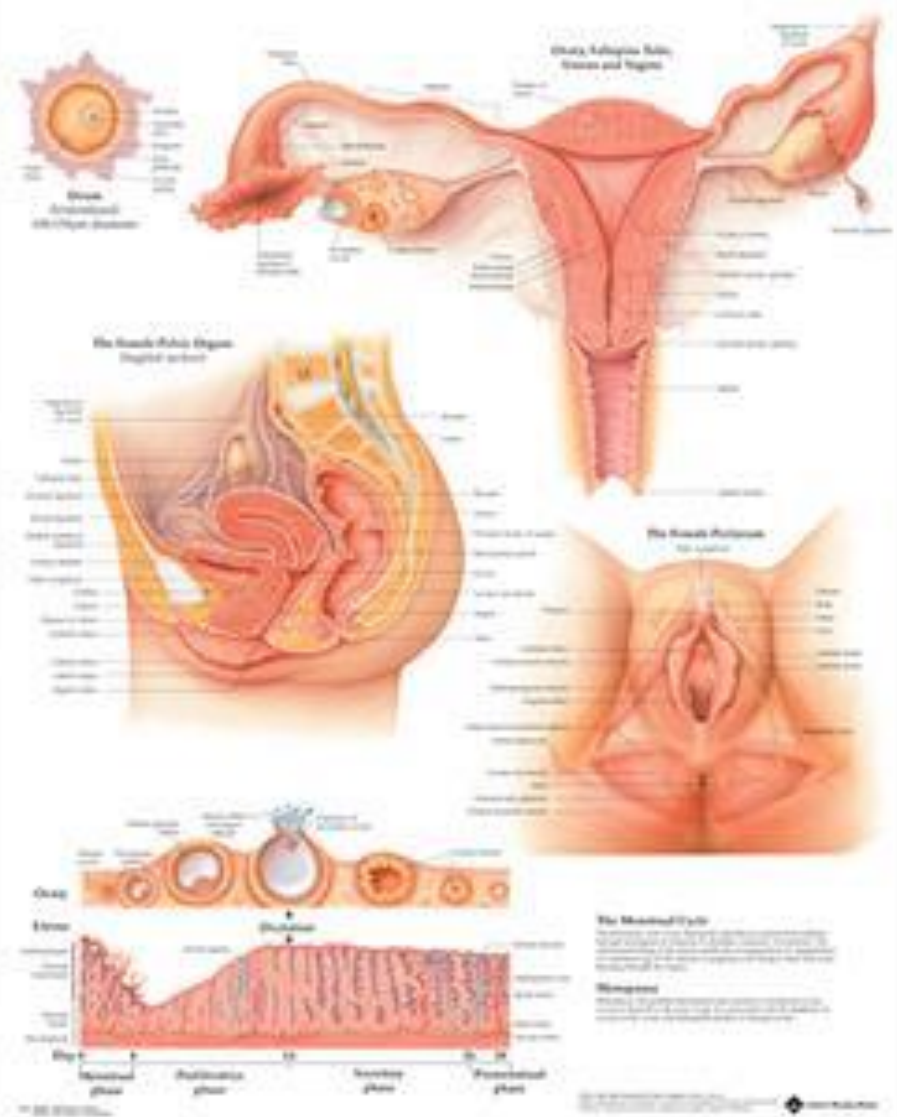
- Meningococcal pneumonia/year – 150
- Pertussis – 20
- Tetanus – 4
- Diphtheria - 0
- HPV related cancers - >4000

“20 times more likely to die of HPV related cancer than the other 4 diseases put together”

Use Visual Aids



THE FEMALE REPRODUCTIVE SYSTEM



THE MALE REPRODUCTIVE SYSTEM





A follow up question
requires the client to
Integrate Information

How would that be for you?

Has that ever happened before?

How did you manage it?

Do you have a sense of how you
would manage it?

Provider Recommendation

Provider recommendation has been shown to be **the most important factor** across ethnicities, gender, race, SES, sexual preference and age groups.

“I strongly recommend you get this immunization.”

“This immunization protects you from many common types of cancer.”

This goes in the SHARE part of an ASA Cycle.

Give a Strong Recommendation

- A strong provider recommendation is a key predictor of a patient receiving a vaccine.
- 66% of patients who received a provider recommendation for influenza vaccine received it within 12 months vs. 16% of those who did not get a recommendation.
- “We have some shots to do today.” vs. “Are we doing shots today?”

Nabet, B. (2017) *Policy Lab at Children’s Hospital of Philadelphia*
CDC(2015) *Epidemiology and Prevention of Vaccine-Preventable Diseases*.
Nowak, GJ. (2018) *Int J Environ Res Public Health*

For Previously Unvaccinated Individuals Offer/Recommend

- Individuals treated or undergoing treatment for CIN2+
- Individuals with current CIN2+ or history of CIN2+ regardless of whether they had surgical treatment
- HCPs routinely exposed to HPV through their occupation
- Individuals who have, plan to have, or hope to have new sexual partner(s)
- Individuals who have had no or minimal sexual contact with others
- Individuals breaking up with a long-term partner

Shared Clinical Decision-Making Recommendations

- For shared clinical decision-making recommendations, there is no default
- There is not a prescribed set of considerations or decision points in the decision-making process
- The decision about whether to vaccinate is informed by:
 - the best available evidence of who may benefit from vaccination
 - the individual's characteristics, values, and preferences
 - the HCP's clinical discretion

Address Barrier

- Use ASA Cycles; affirm before giving information.
- Explore concerns before offering arguments.

Recommendations To Improve Coverage

- Reminder/recall systems, registries
- Standing orders
- Staff education
- Minimize patient out-of-pocket expense
 - Providers enroll in Vaccines for Children (VFC) program
 - “MVPAP’ <http://www.merck.com/Merck/helps/vaccines/home.html>
- Identify barriers in your setting (office hours)

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